June 7, 2021

Nature Communications Publishes Study of CytoDyn's Leronlimab Preventing HIV Infection in Primates

Leronlimab to be studied as potential HIV PrEP drug in humans through an early clinical trial

VANCOUVER, Washington, June 07, 2021 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab, a CCR5 antagonist with the potential for multiple therapeutic indications, announced today the publication in *Nature Communications* of a study showing leronlimab prevented nonhuman primates from being infected with Simian Human Immunodeficiency virus (SHIV), a monkey-human chimeric form of HIV. The results will inform a future human clinical trial evaluating leronlimab as a potential pre-exposure prophylaxis, or PrEP, therapy to prevent human infection from the virus that causes AIDs. "Antibody-based CCR5 Blockade Protects Macaques from Mucosal SHIV Transmission" can be found at: **https://rdcu.be/cl4lv**.

"Our study findings indicate leronlimab could be a new weapon against the HIV epidemic," said the study's lead researcher and co-corresponding author of this paper, Jonah Sacha, Ph.D., an Oregon Health & Science University professor at OHSU's Oregon National Primate Center and Vaccine & Gene Therapy Institute. Dr. Sacha receives compensation as a consultant to CytoDyn and an annual stock option as a member of CytoDyn's Scientific Advisory Board.

"The results of this pre-clinical study, targeting the HIV co-receptor CCR5, have the potential to be groundbreaking as we essentially have a tool that can mimic the genetic mutations of CCR5 that render some individuals immune to infection and have led in part to two cases of a cure of HIV," said the other co-corresponding author, Lishomwa Ndhlovu, M.D., Ph.D., a professor of immunology in medicine at Weill Cornell Medicine in New York. Dr. Ndhlovu receives an annual stock option as a member of CytoDyn's Scientific Advisory Board.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, noted, "We are very thankful to Drs. Sacha and Ndhlovu for their contributions to this important study and very much look forward to the future PrEP trial to prevent human infection of the AIDs virus. PrEP drugs currently available can lead to adverse side effects such as kidney and bone problems, side effects we have not seen with leronlimab. The potential use of leronlimab in multiple therapeutic indications is exciting (i.e., HIV, NASH, cancer, COVID-19). The Company is continuing to advance these opportunities as quickly as possible, including assessing the most cost-effective location to perform its clinical trials, especially considering its new international partners. I am so grateful to work with colleagues who share our vision and dedication to bring leronlimab to market."

About Leronlimab
The U.S. Food and Drug Administration (FDA) granted CytoDyn Fast Track designation to explore two potential indications using leronlimab to treat Human Immunodeficiency Virus (HIV) and metastatic cancer. The first indication is combination therapy with HAART for HIV-infected patients, and the second is for metastatic triple-negative breast cancer (mTNBC). Leronlimab is an investigational humanized IgG4 mAb that binds to CCR5, a cellular receptor important in HIV infection, tumor metastases, and other diseases, including nonalcoholic steatohepatitis (NASH). Leronlimab has been studied in 16 clinical trials involving more than 1,200 people and met its primary endpoints in a pivotal Phase 3 trial (leronlimab combined with HIV standard care in patients with multi-drug resistance to current available classes of HIV drugs).

Leronlimab amongst many things, is a viral-entry inhibitor in HIV/AIDS. It binds to CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Leronlimab does not work on other strains of HIV (for example X4), however R5 is the most dominant strain of HIV. Five clinical trials have demonstrated leronlimab could significantly reduce or control HIV viral load in humans. The leronlimab antibody appears to be a powerful antiviral agent with fewer side effects and less frequent dosing requirements than currently used daily drug therapies. Cancer research has shown CCR5 may play a role in tumor invasion, metastases, and tumor microenvironment control (for example, through angiogenesis). Published studies have shown that blocking CCR5 can reduce tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. Leronlimab reduced human breast cancer metastasis by more than 97% in a murine xenograft model. As a result, CytoDyn is conducting two clinical trials, one, a phase 1b/2 in mTNBC, which was granted Fast Track designation by the FDA in 2019, and a second, a phase 2, basket trial which encompasses 22 different solid tumor cancers.

The CCR5 receptor plays a central role in modulating immune cell trafficking to sites of inflammation. After completing two clinical trials with COVID-19 patients (a Phase 2 and a Phase 3), CytoDyn initiated a Phase 2 investigative trial for post-acute sequelae of SARS COV-2 (PASC), also known as COVID-19 Long-Haulers. This trial will evaluate the effect of leronlimab on clinical symptoms and laboratory biomarkers to further understand the pathophysiology of PASC. It is currently estimated that between 10-30% of those infected with COVID-19 develop long-term sequelae. Common symptoms include fatigue, cognitive impairment, sleep disorders, and shortness of breath. If this trial is successful, CytoDyn plans to pursue clinical trials to evaluate leronlimab's effect on immunological dysregulation in other post-viral syndromes, including myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS).

CytoDyn is also conducting a Phase 2 clinical trial for NASH to evaluate the effect of leronlimab on liver steatosis and fibrosis. Preclinical studies revealed a significant reduction in NAFLD and a reduction in liver fibrosis using leronlimab. There are currently no FDA approved treatments for NASH. NASH is a leading cause of liver transplant. About 30 to 40 percent of adults in the U.S. live with NAFLD, and 3 to 12 percent of adults in the U.S. live with NASH. There have been no strong safety signals identified in patients administered leronlimab in multiple disease spectrums, including patients with HIV, COVID-19 and oncology.

About CytoDyn

CytoDyn is a late-stage biotechnology company developing innovative treatments for multiple therapeutic indications using leronlimab, a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 plays a critical role in the ability of HIV to enter and infect healthy T-cells and appears to be implicated in tumor metastasis and immune-mediated illnesses, such as NASH.

CytoDyn has successfully completed a Phase 2b pivotal trial using leronlimab combined with standard antiretroviral therapies in HIV-infected patients who were heavily treatment-experienced individuals with limited treatment options. CytoDyn has been working diligently to refile its Biologics License Application ("BLA") for this HIV combination therapy since receiving a Refusal to File in July 2020 and subsequently meeting with the FDA telephonically to address their written guidance concerning the filing. CytoDyn expects to refile its BLA in the first half of the calendar year 2021 or shortly thereafter. CytoDyn also completed a Phase 2b/3 investigative trial with leronlimab used as a once-weekly monotherapy for HIV-infected patients. CytoDyn plans to initiate a registration-directed study of leronlimab monotherapy indication. If successful, it could support a label extension approval. Clinical results to date from two trials have shown that leronlimab can keep the viral load suppressed in a sub-population of R5 HIV patients who chose to switch from their daily pills regimen to once a week subcutaneous dose of leronlimab. . Several patients on leronlimab's Phase 2b extension arm have remained virally suppressed for almost 7 years and many patients in our Phase 2b/3 investigative trial are passing two and some four years of monotherapy with suppressed viral load.

CytoDyn is also conducting a Phase 2 clinical trial with leronlimab in mTNBC, a Phase 2 basket trial in solid tumor cancers (22 different cancer indications), Phase 2 investigative trial for post-acute sequelae of SARS COV-2, also known as COVID-19 long haulers, and a Phase 2 clinical trial for NASH. CytoDyn has already completed a Phase 2 and Phase 3 trial for mild to moderate and severe to critical COVID-19 patients, respectively. More information is at www.cytodyn.com.**

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****The forward-looking statement set forth below was inadvertently omitted from the issued release and is incorporated herein.**

Forward-Looking Statements
This press release contains certain forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Examples of such forward-looking statements include, but are not limited to, statements about the potential for leronlimab as a potential pre-exposure, or PrEP therapy, our plans with respect to clinical trials and studies or other programs, and our ability to advance these opportunities. Forward-looking statements involve risks, uncertainties and assumptions that are difficult to predict. The Company's forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such forward-looking statements. The Company urges investors to consider specifically the various risk factors

identified in its most recent Form 10-K, and any risk factors or cautionary statements included in any subsequent Form 10-Q or Form 8-K, filed with the Securities and Exchange Commission. Except as required by law, the Company does not undertake any responsibility to update any forward-looking statements to take into account events or circumstances that occur after the date of this press release.

Source: CytoDyn Inc.